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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/513,910	02/25/2000	Jeffrey Burbank	9313.16739-1	7072

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EXAMINER
BIANCO, PATRICIA

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3762	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/513,910	Applicant(s) BURBANK ET AL.	
	Examiner Patricia M Bianco	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 13-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-12,29-31 and 33-36* is/are rejected.

7)☒ Claim(s) *32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 February 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II, claims 6-12 & 29-36 in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-5 & 13-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Oath/Declaration

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration in a continuation-in-part application filed under the conditions specified in 35 U.S.C. 120 which discloses and claims subject matter in addition to that disclosed in the prior co-pending application, acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

Drawings

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

- figure 9 does not include **368**
- figures 14 & 15 doe not include **136, 138, 145, 155, 201, 203**
- figure 17 does not include **94**

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description:

- **155** shown in figures 14 & 15

A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

7. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. The following are not shown in the drawings: *the replacement fluid path terminating in multiple branches, each including a connector (claim 9); the replacement fluid path including a separate replacement fluid set comprising multiple branches, each branch including a connector, and the replacement fluid path including a set connector (claim 10); the sterilizing filter in the separate replacement set (claim 11); the sterilizing filter in the replacement fluid path upstream of the set connector (claim 12).* All must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

8. Applicant has indicated co-pending applications in the first paragraph of the specification. The first page of the specification should be updated to clarify the status of all related applications noted in the first paragraph of the specification. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

9. The use of the trademark **ACUCHMINA™** has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

10. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-12 recite the limitation " *the replacement fluid path including a separate replacement fluid set comprising multiple branches, each branch including a connector, and the replacement fluid path including a set connector (claim 10); the sterilizing filter in the separate replacement set (claim 11); the sterilizing filter in the replacement fluid path upstream of the set connector (claim 12).*" There is insufficient antecedent basis in the specification and drawings as originally filed for these limitations in the claims.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Polaschegg et al. (7,702,829). Polaschegg et al. (hereafter Polaschegg) discloses a hemodiafiltration system including an extracorporeal circuit which circulates blood from an individual through a hemofilter such that waste is removed, replacement fluid is added to the blood downstream of the filter, and the combined waste-free blood and replacement fluid is returned to the patient. The extracorporeal circuit includes a replacement fluid path, shown in the figure as line 90, tubing 94, and connectors 100 & 116. The replacement fluid circuit further includes a microfilter (98), which is integral with the line and tubing for removing pyrogens from the replacement fluid. The dashed lines in the figure also define the replacement fluid circuit. The replacement fluid may be added to the treated blood at location 116. (See col. 5, line 36-col. 6, line 50). The claim limitations that the extracorporeal circuit "for circulating blood....through a hemofilter to remove waste..." and of the replacement fluid path "to convey replacement fluid from a source to the extracorporeal circuit" in claims 1 & 6 have been treated as intended use recitations. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the

claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham,* 2 USPQ2d 1647 (1987). Since neither the hemofilter nor source has been positively claimed, it the position of the examiner that the circuits in the system of Polaschegg are capable of connecting to a hemofilter and to a source.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polaschegg et al. ('829) in view of Jonkman et al. (5,423,769). Polaschegg discloses the invention substantially as claimed, see rejection supra. Polaschegg, however, fails to disclose specifically that the replacement fluid path terminating in multiple branches,

each including a connector; the replacement fluid path including a separate replacement fluid set comprising multiple branches, each branch including a connector, and the replacement fluid path including a set connector; the sterilizing filter in the separate replacement set; and that the sterilizing filter in the replacement fluid path upstream of the set connector.

Jonkman et al. (hereafter Jonkman) discloses a tubing set (12) having multiple branches (20/24/26) having luer fittings (46/48/50) or connectors disposed on the distal ends. It is well known in the medical art to use luer fittings to connect tubing to containers holding medicinal fluids. Therefore, it would have been obvious to one having skill in the art at the time of the invention to modify the system of Polaschegg to include a tubing set having multiple branches, each with a connector, that may be connected to a source of replacement fluid or components thereof. It is well known that replacement fluid is added to change or correct the blood properties, such as pH level and/or the concentration of the necessary electrolytes, Na, K, Cl, Ca, Mg, and combinations thereof. Therefore, using multiple source containers, each connected to an individual tubing branch, would allow more selective addition of substances as needed.

14. Claims 29-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manica (5,679,245) in view of Polaschegg ('829). Manica discloses the invention substantially as claimed, however fails to disclose specifically a method for performing hemofiltration including a hemofiltration unit (40) or machine and a replacement fluid

circuit. The entire system is under microprocessor control. During use, a patient's blood is withdrawn, passed through the hemofiltration unit to remove waste fluid and replacement fluid is added as needed (see fig. 2, col. 3, line 3-col. 8, line 20; col. 11, line 60-col. 13, line 64). Manica discloses the invention substantially as claimed, however, fails to disclose specifically the following: that the replacement fluid path includes a sterilizing filter in the fluid path; the steps (i) to (iii) are conducted during multiple intermittent sessions of a predetermined time period, specifically from about 48 hours to about 120 hours; performing steps (i) to (iii) at least four times weekly; and wherein the blood is conveyed through the hemofilter at a flow rate of at least about 300 ml/min.

Polaschegg discloses a replacement fluid path as part of an extracorporeal blood circuit, which includes a microfilter integral with the line, and tubing for removing pyrogens from the replacement fluid, see rejection supra. At the time of the invention, it would have been obvious to one having ordinary skill in the art to modify the replacement circuit of Manica to include a microfilter as taught by Polaschegg to ensure that the replacement fluid being added to the patient's treated blood is free of pyrogens.

With respect to the steps (i) to (iii) are conducted during multiple intermittent sessions of a predetermined time period, specifically from about 48 hours to about 120 hours, or the step of performing steps (i) to (iii) at least four times weekly, at the time of the invention it would have been obvious for one having skill in the art to modify the treatment protocol to include any of these limitations, since discovering the optimum or workable ranges involves only routine skill in the art since applicant has not disclosed

that any of these steps solve any stated problem or is for any particular purpose these modifications would be within the ordinary skill in the art. Therefore, repeating the steps "at least four times weekly" or "during intermittent sessions, specifically from about 48 hours to about 120 hours" would involve only routine skill in the art. Also, these steps would be chosen on an individual basis, depending on the patient undergoing the treatment at a given time, since each patient will require individualized course of action.

With respect to the step of conveying the blood through the hemofilter at a flow rate of at least about 300 ml/min, Manica teaches that the controller operated pumps may be set to a desired or appropriate blood flow rate. Therefore, at the time of the invention it would be obvious to convey blood at this rate if one desired, since it has been held where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. Therefore, modifying the pump speed to an optimum operating blood flow rate of at least 300 mL/min would involve only routine skill in the art.

Allowable Subject Matter

15. Claim 32 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The subject matter not found was the step of subjecting the extracorporeal circuit to refrigeration between multiple intermittent sessions in addition to the other claimed limitations.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Schael and Jonsson disclose preparation of substitute or replacement fluids including sterilization via an inline filter before delivery to the patient for use in medical methods.

Collins et al. ('631 & '231) disclose hemodiafiltration systems and methods wherein substitution fluid is generated on-line, from spent dialysate fluid, by passing through a sterility filter prior to delivery to the patient.

17. Any inquiry concerning the rejections contained within this communication or earlier communications should be directed to examiner Tricia Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays, alternating Fridays off, from 9:00 AM until 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The official fax numbers for the organization where this application or proceeding is assigned is (703) 872-9302 for regular communications and for After Final communications (703) 872-9303.

Tricia Bianco
Patent Examiner
Art Unit 3762

pmb TBianco
April 5th, 2003